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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/916,257	07/30/2001	Alla Shapiro	7505.100	1216

7590

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Karen L. Orzechowski
Liniak, Berenato, Longacre & White, LLC
Suite 240
6550 Rock Spring Drive
Bethesda, MD 20817

EXAMINER

SHARAREH, SHAHNAM J

ART UNIT

PAPER NUMBER

1617

DATE MAILED: 08/13/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/916,257

Applicant(s)

SHAPIRO, ALLA

Examiner

Shahnam Sharareh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 May 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9, 17-25 and 29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 and 17-25, 29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

1. Amendment filed on May 12, 2003 has been entered. Claims 1-9, 17-25, 29 are pending. Any rejection that is not addressed in this Office Action is considered obviated in view of the amendment.

Claim Rejections - 35 USC § 102

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Claims 1, 4 stand rejected under 35 U.S.C. 102(b) as being anticipated by Wei et al US Patent 5,824,702.

Applicant arguments with to this rejection have been fully considered but are not found persuasive. Applicant argues that Wie does not employ the isoflavone for treating harmful effects of ionizing radiations.

As the initial matter, the instant claims are directed to methods of treating the harmful effects of ionizing radiation throughout the entire body of a mammal exposed to radiation comprising administering to said mammal a therapeutically effective amount of isoflavone. Accordingly, the only active step in the claimed methods involves administration of isoflavone.

In response to Applicant's arguments, Examiner states that under the principles of inherency, a prior art that does not expressly disclose claim limitations anticipates the claims, if it necessarily functions in accordance with, or includes, those limitations. *Atlas Powder Co. v. IRECO Inc.* 190 F.3d 1342, 1349 (Fed. Cir. 1999). Inherency is not necessarily coterminus with knowledge of those of ordinary skill in art, since artisans of

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ordinary skill may not recognize inherent characteristics or functioning of prior art, but discovery of previously unappreciated property of prior art composition or of scientific explanation for prior art's functioning, does not render old compositions patentably new to discoverer. *Id.* Accordingly, a prior art reference may anticipate when the claim limitation or limitations not expressly found in that reference are nonetheless inherent in it. *Verdegaal Bros., Inc. v. Union Oil Co. of Cal.*, 814 F.2d 628, 630 (Fed. Cir. 1987).

In the instant claims, the only functional step requires administration of a therapeutically effective amount of an isoflavone. Wei teaches this step by administering similar dosage forms as instantly claims. Therefore, Wei's method inherently provides for the intended use of the instant claims.

4. Claims 1, 4 stand rejected under 35 U.S.C. 102(e) as being anticipated by de Juan Jr. US Patent 6,399,655 or Lanzendorfer et al US Patent 6,423,747.

Applicant's arguments with respect to these references have been fully considered but are not persuasive. Applicant argues that de Juan and Lanzendorfer do not use their compositions for treating ionizing radiation. However, in response, Examiner relies on the inherency arguments set forth above. Accordingly, since de Juan and Lanzendorfer administer their isoflavones in the same amount as instantly claimed, they inherently anticipate the limitations of the instant claims.

Claim Rejections - 35 USC § 103

5. Claims 1-9, 17-25, 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brown et al US Patent 6,528,042 in view of Uckun et al. Proc. Natl. Acad. Sci. USA, 89, 9005 (1992) in view of de Juan Jr. US Patent 6,399,655 .

Brown teaches methods of ameliorating the disruption of energy metabolism secondary to an environmental stress such as ionizing radiation comprising administering to a subject a flavonoid within the instantly claimed ranges. (see abstract, col 12, line 40; col 14, line 8-12; col 21, lines 55-col 22, line 65). Accordingly, Brown is viewed to alleviate or treat potential side effects caused by ionizing radiation.

Uckun supplements the teachings of Brown as it explicitly provides that genistein has been shown to prevent apoptosis in cells which have undergone ionizing radiation or engagement of the CD19 receptor. (see abstract, and page 9008, 4-6 para.). In fact, Uckun teaches that ionizing radiation is standard therapy for B cell malignancies such as leukemias and lymphomas and that ionizing radiation stimulates B cell tyrosine kinases, triggering apoptosis and clonogenic cell death. Accordingly, Uckun concludes that tyrosine kinase inhibitors such as genistein blocked the radiation-induced tyrosine phosphorylation and apoptosis. In effect, Uckun provides ample motivation in the art to use isoflavones such as genistein to at least treat one harmful side effect of ionizing radiation.

Brown and Uckun fail to discuss administrations of their compositions in a mammal.

De Juan is solely used to show that systemic application of genistein is well established in the art (cols 9-11).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time of invention to administer genistein for treating ionizing radiation associated side effects and further as described by Brown and de Juan optimize the useful doses by

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routine experimentation. One of ordinary skill in the art would have been motivated to do such modifications because as suggested by Brown and Uckun, genistein would have been expected to alleviate side effects caused by ionizing radiation.

Claim Objections

The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered claim 26 been renumbered 29, because claim 26 has already been canceled.

Conclusion

6. No claims are allowed. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action, because the scope of the claims have been modified. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh whose telephone number is 703-306-5400. The examiner can normally be reached on 8:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, PhD can be reached on 703-308-1877. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1123.

SS
August 11, 2003


RUSSELL TRAVERS
PRIMARY EXAMINER